

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
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## PCT

REC'D 22 JUN 2005

WIPO PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) **20 JUN 2005**

Applicant's or agent's file reference

14074-015WO1

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/43600

International filing date (day/month/year)

27 December 2004 (27.12.2004)

Priority date (day/month/year)

30 December 2003 (30.12.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C08K 5/34, 5/52; C08L 67/04, 67/06 and US Cl.: 524/99, 100, 104, 119, 599, 601, 604, 605

Applicant

METABOLIX, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/43600

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US04/43600

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>6-18, 26-41, 45, 50, and 51</u>	YES
	Claims <u>1-5, 19-25, 42-44, and 46-49</u>	NO
Inventive step (IS)	Claims <u>6-18 and 45</u>	YES
	Claims <u>1-5, 19-44, and 46-51</u>	NO
Industrial applicability (IA)	Claims <u>1-51</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and explanations:**

Claims 6-18 and 45 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the use of a nucleant comprising nitrogen-containing heteroaromatic core with polyhydroxyalkanoates or aromatic polyesters.

Claims 1-5, 19-25, and 42-44 lack novelty under PCT Article 33(2) as being anticipated by Takasa et al (US 4,946,930). Takasa et al discloses a biaxially-oriented film (abstract) comprising organic nucleating agents (col. 5, lines 12-17) and polyester (col. 8, lines 35-36) and/or polyolefins (col. 8, lines 17-23).

In light of the above, it is clear that the presently cited claims lack novelty over Takasa et al.

Claims 46-49 lack novelty under PCT Article 33(2) as being anticipated by Matsushita et al (US 6,515,054 B1).

Matsushita et al discloses a biodegradable resin composition comprising polyester resin (col. 5, lines 11-36); and a nucleating agent such as sorbitol derivatives (col. 11, line 36 to col. 12, line 17); and an organic solvent (col. 8, lines 52-54) which are all mixed together and subsequently molded into an article such as a film (col. 12, line 61 to col. 13, line 64).

Claims 50 and 51 lack an inventive step under PCT Article 33(3) as being obvious over Matsushita et al (US 6,515,054 B1).

Although Matsushita et al does not teach a copolymer of the polyhydroxyalkanoates, it would have been obvious to one of ordinary skill in the art to utilize known biodegradable copolymers based on hydroxyalkanoates utilizing any combination of hydroxycarboxylic acids as disclosed in col. 3, line 66 to col. 4, line 8 in any amount, including those presently claimed.

Claims 26-41 lack an inventive step under PCT Article 33(3) as being obvious over Matsushita et al (US 6,515,054 B1) in view of Ishii et al (US 5,693,285 A).

Matsushita et al does not expressly disclose the use of a metal salt of cyclic organophosphoric esters as nucleating agents in its composition, however, note that Matsushita et al is open to the use of a variety of effective nucleating agents, including metal salt of phosphoric acid (col. 12, lines 11-13).

Ishii et al teaches a plurality of effective nucleating agents, including those taught by Matsushita et al (col. 3, line 28 to col. 4, line 22). Furthermore, Ishii et al teaches the use of cyclic organophosphoric esters such as those on col. 3, line 54 to col. 4, line 6 (e.g., aluminum-2,2'-methylene-bis(4,6-di-t-butylphenyl)phosphate).

Given that the presently claimed cyclic organophosphoric ester is a known nucleating agent as taught by Ishii et al, it would have been obvious to one of ordinary skill in the art to utilize such a nucleating agent in the composition of Matsushita et al and thereby arrive at the presently cited claims.

Claims 1-51 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

**WRITTEN OPINION OF THE  
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International application No.

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**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 3 objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 3 and 51 are indefinite for the following reason(s):

With respect to claim 3, R is not defined and there is no  $R^2$  in the formulae.

With respect to claim 51, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/43600

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(7) : C08K 5/34, 5/52; C08L 67/04, 67/06 US CL : 524/99, 100, 104, 119, 599, 601, 604, 605 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 524/99, 100, 104, 119, 599, 601, 604, 605 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO, JPO, and Derwent Databases		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ✓	US 4,946,930 A (TAKASA et al) 7 August 1990 (07.08.1990), col. 5, lines 12-17; col. 8, lines 17-23 and 35-36.	1-5, 19-25, and 42-44
X ✓	US 6,515,054 B1 (MATSUSHITA et al) 4 February 2003 (04.02.2003), column 5, lines 11-36; column 8, lines 52-54; column 11, line 36 to column 12, line 17; column 12, line 61 to column 13, line 64.	46-51 ----- 26-41
Y ✓	US 5,693,285 A (ISHII et al) 2 December 1997 (02.12.1997), column 3, line 28 to column 4, line 22.	26-41
A ✓	US 3,563,971 A (WOOD et al) 16 February 1971 (16.02.1971), abstract, claim 1-9.	1-25 and 42-45
A ✓	JP 06-340786 A (ASAHI DENKA KOGYO KK) 13 December 1994 (13.12.1994), abstract.	26-41
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 02 June 2005 (02.06.2005)		Date of mailing of the international search report 20 JUN 2005
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Vickey Ronesi Telephone No. (571) 272-1700 